

REMARKS

I. Basis for Amendments

The cross reference to related applications in the specification has been updated in response to the examiner's request.

Claim 16 has been amended to more clearly define the invention by incorporating the feature previously recited in claim 27, which has been cancelled. Applicants reserve the right to pursue cancelled subject matter in a continuing application. Support for the amendment can be found in the specification, for example, in paragraph [0019], lines 1-2, at page 6.

Claims 16-18 are now pending. For reasons discussed below, these claims are allowable.

II. The Claims Are Patentable Under 35 U.S.C. § 112, First Paragraph

Claims 16-18 have been rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. In particular, the Examiner argued that the recitation of "homogeneous" population of purified immobilized empty MHC Class I molecules lacks basis in the original disclosure. To obviate this rejection, applicants have amended the claim 16 to remove the descriptive limitation. Support for the amendment can be found in the specification, for example, in paragraph [0019], lines 1-2, at page 6. Accordingly, this rejection has been overcome.

II. The Claims Are Novel Under 35 U.S.C. § 102(b)

Claims 16-18 and 27 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Burshtyn et al. (*J. Immunol.* 151: 3070-3080, 1993). Applicants traverse the rejection.

The Office Action cites the Burshtyn et al. reference as teaching a substrate for capturing antigens. The Burshtyn et al. reference utilizes a source of MHC Class I molecules that are isolated by immunoisolation from RMA and RMA-S mammalian cell lines. See Burshtyn et al., p. 3071, col. 1, paragraph 2, and col. 2, paragraph 3. The MHC Class I molecules are immunoisolated to "relatively high purity." By contrast, the presently claimed substrate comprises a support having on its surface a population of purified immobilized

empty MHC Class I molecules, where the MHC Class I molecules are K^{bm3} or L^D molecules expressed from a recombinant *Drosophila* cell and are capable of binding one or more antigens, and where the substrate is not a lipid bilayer. Regarding this difference, the examiner asserted that, absent a showing that there is a physical difference, empty human MHC Class I complexes expressed in and purified from recombinant *Drosophila* cells and empty human MHC Class I complexes expressed in and purified from mammalian cell lines are viewed as being the same. The examiner's assertion boils down to an improper inherency rejection.

To establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the feature described in the reference, and that it would be so recognized by persons of ordinary skill in the art. See *In re Robertson*, 169 F.2d 743, 49 U.S.P.Q.2d 1949 (Fed. Cir. 1999). Here, no reasoned explanation is provided or extrinsic evidence is cited to show that persons of ordinary skill in the art would recognize the MHC Class I complexes of Burshtyn et al. to be the same as those of the claimed substrate. Inherency may not be established by probabilities or possibilities. *Id.*

Moreover, the extrinsic evidence negates, rather than supports, inherency in the disclosure of the reference. For example, MHC Class I molecules expressed in and purified from recombinant *Drosophila* cells have physical differences or characteristics compared to MHC Class I molecules purified from mammalian cell lines. As explained in Jackson et al., *Proc. Natl. Acad. Sci. USA* 89: 12117-12121, 1992 (Exhibit A), abstract “transfected *Drosophila melanogaster* cells can express large quantities of Class I major histocompatibility complex molecules. Such molecules lack endogenous peptides because *Drosophila* cells are devoid of proteins necessary for intracellular peptide loading.” Thus, a higher percentage of empty MHC Class I molecules can be purified from recombinant *Drosophila* cells as compared to MHC Class I complexes purified from mammalian cell lines.

Since the Burshtyn et al. reference fails to disclose a substrate expressly or inherently comprising a support having on its surface a population of purified immobilized empty MHC Class I molecules, where the MHC Class I molecules are K^{bm3} or L^D molecules expressed from a recombinant *Drosophila* cell, the Section 102 rejection is in error and should be withdrawn.

III. The Claims Are Patentable Under 35 U.S.C. § 103(a)

The rejection of claims 16-18 and 27 under 35 U.S.C. § 103(a) as allegedly being obvious from Burshtyn et al. is also in error.

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation to modify the reference or to combine the reference teachings so as to arrive at the claimed invention and there must be a reasonable expectation of success for achieving the claimed invention as a whole. See *In re Vaeck*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Here, a proper *prima facie* case of obviousness has not been set forth.

Independent claim 16 is directed to a substrate for capturing antigens, comprising a support having on its surface a population of purified immobilized empty MHC Class I molecules, wherein said MHC Class I molecules are K^{bm3} or L^D molecules expressed from a recombinant *Drosophila* cell and are capable of binding one or more antigens, and wherein said substrate is not a lipid bilayer. The cited references fail to teach or suggest such a substrate.

As noted above, the Office Action cites the Burshtyn et al. reference as teaching a substrate for capturing antigens. The Burshtyn et al. reference utilizes a source of MHC Class I molecules that are purified by immunoisolation from mammalian RMA and RMA-S cells. The Burshtyn et al. reference, however, does not teach or suggest MHC Class I molecules expressed in and purified from recombinant *Drosophila* cells. The Nikolic-Zugic et al. reference does not cure the deficiencies of the Burshtyn et al. reference. The Nikolic-Zugic et al. reference was cited as teaching the use of K^{bm3} Class I molecule-expressing APCs for presentation to T cells. But the secondary reference, like the primary reference, merely discloses the use of mammalian cells to produce the MHC Class I molecules. The Office Action further cites. Since both references lack any teaching or suggestion of employing K^{bm3} or L^D molecules expressed from a recombinant *Drosophila* cell that are capable of binding one or more antigens as in the claimed substrate, the claims patentably define over the prior art. Applicants therefore request that the rejection of claims 16-18 under 35 U.S.C. § 103(a) be withdrawn.

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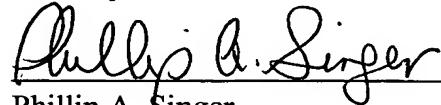
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IV. Conclusion

In view of the foregoing, the application is now in condition for allowance. The prompt issuance of a formal Notice of Allowance is therefore requested.

If the Examiner believes a telephone conference would expedite allowance of this application, please telephone the undersigned at 206-332-1380.

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Enclosure:

Exhibit A

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